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Attorney Docket No. 103419-0003 (fka J-EPLEY.1002)

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Epley, John M.

Serial No. 10/715,871

Examiner: Hoekstra, Jeffrey Gerben

Confirmation No. 5600

Filed: November 17, 2003

Group Art Unit: 3736

For: HEAD-STABILIZED MEDICAL APPARATUS, SYSTEM AND METHODOLOGY

Date: January 19, 2007

Mail Stop AF  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450**PRE-APPEAL BRIEF REQUEST FOR REVIEW**

Applicant respectfully requests review of the final rejection in the Office Action mailed on October 23, 2006 in the above-identified application. The assertions underlying each claim rejection in the office action are based upon clear legal and factual errors, and the cited references fail to teach or suggest all the claim limitations of any claim as detailed hererin. As a result, the office action fails to establish a *prima facie* case of unpatentability under 35 §102(b) regarding any of the claims rejected in the final office action. A Notice of Appeal is filed herewith.

**Clear Factual Errors Regarding Rejections Under 35 §102(b)**

Claims 1-8 and 20-23 stand rejected under 35 §102(b) as anticipated by U.S. Pat. 6,159,171 to Densert et al. (hereinafter DENSERT).

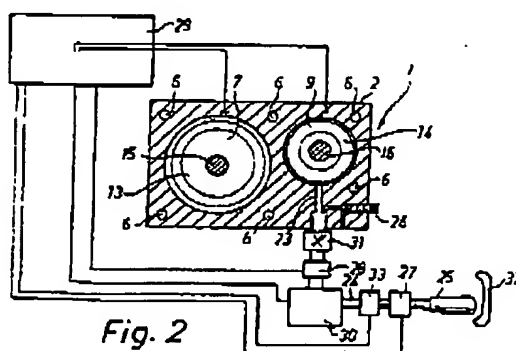
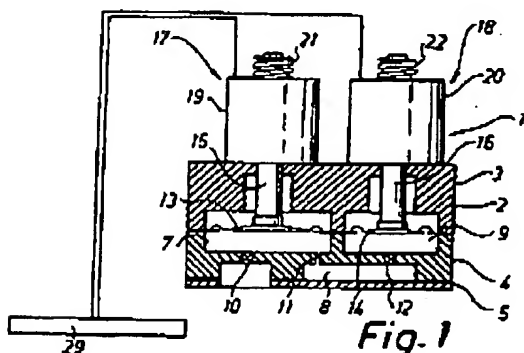
- Independent claim 1 recites: "Apparatus . . . comprising . . . head-wearable frame structure adapted for wearing on a subject's head in a condition thereon of relative positional stability",

- Independent claim 7 recites: "Apparatus . . . comprising . . . frame structure wearably securable to a subject's head in a manner causing the frame structure to function as a non-relative-motion unit with the head", and
- Independent claim 20 recites: "System . . . comprising . . . headgear worn by a subject, including frame structure seated with positional stability on the subject's head".

"A claim is anticipated only if *each and every* element as set forth in the claim is found, either *expressly or inherently* described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of CA*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987); MPEP §2131 (emphasis provided). DENSERT fails to expressly or inherently describe applicant's recited claim limitations. The Examiner asserts, with regard to claims 1, 7 and 20 collectively, that DENSERT discloses "a stabilized head-dependent wearable frame structure" (Final Office Action, page 2, section 4). However, the Examiner's assertions contain clear factual and legal errors, and the Final Office Action fails to establish a *prima facie* case as required to properly reject independent claims 1, 7, and 20 under 35 U.S.C. §102(b).

#### Regarding Claim 1

Applicant's claim limitations affirmatively recite (1) a "head-wearable frame structure", and further limit the apparatus to only those frame structures that are (2) "adapted for wearing on a subject's head" (3) "in a condition thereon of relative positional stability". A device lacking appropriate structural adaptations can not be worn "on a subject's head in a condition thereon of relative positional stability", and therefore fails to meet the recited claim limitations.



DENSERT completely fails to *explicitly* describe or depict that the 'housing 2' (shown in DENSERT Figs. 1 and 2 above) is "head wearable" or structurally "adapted for wearing on a subject's head", nor does the Examiner indicate any such structural adaptations. Further, the

DENSERT 'housing' would not be so understood by one having ordinary skill in the art except by the impermissible use of hindsight in view of applicant's disclosure. DENSERT fails to disclose such structural adaptations in or to the 'housing'. Therefore, DENSERT factually fails to disclose the indicated claim limitations, and the Examiner's assertion constitutes clear factual error.

The Examiner asserts that the recited limitations constitute "positive recitation of functional language as intentional use", and notes that such recitation "must result in a structural difference between the claimed invention and the prior art". However, the Examiner's construction of applicant's claims constitutes *clear factual and legal error*. Applicant's claims recite that the "head-wearable frame structure" is "adapted for" specific functional requirements. Factually, not all structural adaptations that make a frame structure "head wearable" will provide the same "in a condition thereon of relative positional stability". This latter limitation narrows the scope of structural configurations and adaptations that will meet applicant's claim limitations. Similar to a "whereby" clause, applicants "adapted for" clause "states a condition that is material to patentability", and "cannot be ignored in order to change the substance of the invention" according to the Examiner's construction of the claim, [MPEP 2111.04, quoting *Hoffer v. Microsoft Corp.*, 405 F.3d 1326, 1329, 74 USPQ2d 1481, 1483 (Fed. Cir. 2005).

Absent explicit teaching, DENSERT must inherently disclose applicant's claim limitations for a proper 35 U.S.C. §102 rejection. DENSERT fails in this regard as well. The Examiner asserts that "[i]f the prior art structure is capable of performing the intended use, then it meets the claim", (Advisory Action, January 10, 2007). Following the Examiner's reckoning, the lack of appropriate structural adaptations is no impediment to construing that nearly any item with a 'housing' (e.g., a toaster, a mailbox, a bathroom scale) is "head wearable". These objects are at least as 'adapted for' head wearability as the DENSERT 'housing'. Substantial existing case law demonstrates the Examiner's assertion constitutes *clear legal error*.

"The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic". *In re Rijckaert*, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993); MPEP § 2112(IV)(emphasis original). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter *is necessarily present* in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances *is not sufficient*.'" *In re Roberson*, 169 F.3d 743, 745,

49 USPQ2d 1949, 1950-51 (Fed. Dir. 1999)(emphasis added). “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.” *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990); MPEP § 2112(IV), (emphasis in original).

The examiner provides no basis in fact and/or technical reasoning to reasonably support that the asserted ‘frame’ (housing 2) of DENSERT is *necessarily* either “head-wearable”, or “adapted for wearing on a subject’s head in a condition thereon of relative positional stability”. Rather, the DENSERT housing could be retained and/or mounted in various configurations that do not include being worn on a subject’s head (e.g., on a table, wall, cart), as are innumerable other medical treatment systems and apparatuses. The DENSERT ‘housing’ is no more inherently (necessarily) “adapted for wearing on a subject’s head in a condition thereon of relative positional stability” than the mentioned toaster, mailbox, or bathroom scale. Therefore, DENSERT’s ‘housing’ does not inherently teach applicant’s recited claim limitations.

Further, because the DENSERT ‘housing’ does not have any features, components, or other structural adaptations enabling it to be worn “on a subject’s head in a condition thereon of relative positional stability”, the DENSERT device, as described and depicted is *not capable* of performing the intended use stated and/or implied by applicant’s recited claim limitations. The DENSERT device could only be so worn on a subjects head if the Examiner improperly imports structural teachings into DENSERT that do not presently exist in DENSERT. Therefore, the Examiner’s assertions in this regard constitute another example of *clear factual error*.

Thus, DENSERT neither explicitly nor inherently discloses the indicated limitations recited in applicant’s independent claim 1, and as shown, the Examiner’s assertions contain clear factual and legal errors. For at least these reasons, the Final Office Action fails to establish a *prima facie* case required for a proper rejection of independent claim 1 under 35 U.S.C. 102(b).

#### **Regarding Claim 7**

For the same fundamental reasons that DENSERT fails to disclose the recited limitations of independent claim 1, DENSERT also completely fails to explicitly or inherently disclose that the ‘housing 2’ is a “frame structure [1] wearably securable [2] to a subject’s head [3] in a manner causing the frame structure to function as a non-relative-motion unit with the head”, as recited in applicant’s independent claim 7. Inasmuch as the Examiner collectively and generally levels the identical assertions against both claims 1 and 7, the Examiner’s assertion contains the

same clear factual and legal errors with regard to both claims. Therefore, the Final Office Action also fails to establish a *prima facie* case required for a proper rejection of independent claim 7 under 35 U.S.C. 102(b).

#### Regarding Claim 2


For the same fundamental reasons that DENSERT fails to disclose the recited limitations of independent claims 1 and 7, DENSERT also completely fails to explicitly or inherently disclose that the 'housing 2' is "[1] headgear [2] worn by a subject, [3] including frame structure seated with positional stability [4] on the subject's head", as recited in applicant's independent claim 20. Inasmuch as the Examiner collectively and generally leveled the identical assertion against both claims 1, 7 and 20, the Examiner's assertion contains the same clear factual and legal errors with regard to all three claims. Therefore, the Final Office Action also fails to establish a *prima facie* case required for a proper rejection of independent claim 20 under 35 U.S.C. 102(b).

#### Regarding Dependent Claims 2-6, 8 and 21-23

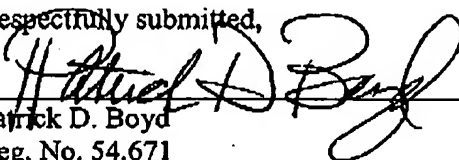
Inasmuch as claims 2-6, 8 and 21-23 depend from and include the limitations of independent claims 1, 7 and 20, respectively, applicant submits that the Final Office Action also fails to establish a *prima facie* case under 35 U.S.C. 102(b) with regard to claims 2-6, 8 and 21-23.

#### Conclusion

In light of the arguments set forth herein, applicant respectfully submits that all rejections asserted in the Final Office Action are shown herein to be improperly based upon clear factual and legal errors, and that a *prima facie* case is not established to support the rejections. Applicant therefore respectfully requests that all claims be allowed without undue delay.

<p>I hereby certify that this correspondence is being transmitted to the U.S. Patent and Trademark Office via facsimile number 571-273-8300 on the following date: January 19, 2007</p> <p> NAME</p>
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Respectfully submitted,

  
Patrick D. Boyd  
Reg. No. 54,671

Customer No. 35940